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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,526	06/24/2003	William R. Noyes	3516.32US01	1769
63274 7590 07/20/2009 DARDI & ASSOCIATES, PLLC 220 S. 6TH ST. SUITE 2000, U.S. BANK PLAZA MINNEAPOLIS, MN 55402				
EXAMINER SHEIKH, HUMERA N				
ART UNIT		PAPER NUMBER		
1615				
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07/20/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/602,526

Applicant(s)

NOYES, WILLIAM R.

Examiner

Humera N. Sheikh

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17, 19, 21-24, 29-38 and 65-73 is/are pending in the application.
- 4a) Of the above claim(s) 29-32, 66-70, 72 and 73 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 65 is/are allowed.
- 6) ☒ Claim(s) 17, 19, 21-24, 33-38 and 71 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of the Application

Receipt of the Response to Restriction/Election requirement and Applicant's Arguments/Remarks, all filed 03/30/09 is acknowledged. Receipt of the Request for Continued Examination (RCE) under 37 C.F.R. 1.114 filed 08/18/08 and the Declaration of Dr. Sawhney, the NPL articles and referenced patents submitted with the RCE of 8/18/08 is also acknowledged.

Applicant's election with traverse of species (h) polyethylene glycol as filler in the reply filed on 03/30/09 is acknowledged. The traversal is on the ground(s) that "the generic claim has already been examined such that there is no undue burden to search all of the species at this juncture" and "issuance of the new restriction requirements is procedurally improper". This is not found persuasive because numerous species have been claimed that are capable of supporting a separate patent within the art. The distinct species claimed would also require a separate search in both patent and non-patent databases and there is no expectation that the searches would be coextensive in scope. This creates an undue burden upon the Examiner. Applicant also traversed the restriction stating that the Restriction/Election was 'procedurally improper'. The Examiner points out that since the Examiner had inadvertently omitted the specific fillers - collagen (species k) and hyaluronic acid (species l) from the previous restriction requirement (dated 11/03/08), the additional restriction requirement of 3/19/09 was submitted in order to provide an accurate record for the election of species and give Applicants a fair opportunity to respond to the complete and corrected version of the restriction requirement.

The requirement is still deemed proper and is therefore made FINAL.

The 35 U.S.C. 112, 1st paragraph rejection of claims 17, 19, 21-24 and 29-38 based on lack of enablement for the specific fillers (i.e., fillers of claim 21) has been maintained since the NPL Articles, Patents and Declaration of Dr. Sawhney with citation to published articles (*I./I. Radiation Oncology*) filed 8/18/08 has not been provided on an Information Disclosure Statement for consideration on the merits (see below under the heading "Information Disclosure Statement").

Claims 29-32, 66-70 and 72-73 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 30 March 2009.

Claims 17, 19, 21-24, 29-38 and 65-73 are pending in this action. Claim 17 has been amended. Claims 29-32, 66-70 and 72-73 have been withdrawn. Claims 1-16, 18, 20, 25-28 and 39-64 have previously been cancelled. Claims 17, 19, 21-24, 33-38 and 71 are rejected. Claim 65 is allowable.

* * * * *

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 18 August 2008 has been entered.

* * * * *

Information Disclosure Statement

The information disclosure statement (particularly the Patents and NPL Articles cited by Applicant) filed 18 August 2008 fails to comply with 37 CFR 1.98(a)(1), which requires the following: (1) a list of all patents, publications, applications, or other information submitted for consideration by the Office; (2) U.S. patents and U.S. patent application publications listed in a section separately from citations of other documents; (3) the application number of the application in which the information disclosure statement is being submitted on each page of the list; (4) a column that provides a blank space next to each document to be considered, for the examiner's initials; and (5) a heading that clearly indicates that the list is an information disclosure statement. The information disclosure statement has been placed in the application file, but the information referred to therein has not been considered.

* * * * *

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17, 19, 21-24, 33-38 and 71 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a biocompatible filler material made of "collagen", does not reasonably provide enablement for the selective filler materials of instant claim 21 (i.e., polyethylene glycol). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the

invention commensurate in scope with these claims. Applicant has only established ample support in the specification for the use of “collagen” as a suitable filler material (specification, pp. 5-6). Applicant has not presented sufficient support for any other embodiment regarding the filler materials of instant claim 21. The specification merely states at page 6, lines 7-9, that, “Other materials may be used that include natural or synthetic materials, e.g., proteins...polyethylene glycol-based materials”. This disclosure is not sufficient to support the species of filler materials of instant claim 21 and is found unpatentable.

Claims 17, 19, 21-24, 33-38 and 71 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a therapeutic dose of radiation to be from 70-100Gy, does not reasonably provide enablement for the generic recitation of a “therapeutic dose of radiation” as is presently claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. Applicant has only established ample support in the specification for the administration of a therapeutic dose of radiation to be from 70-100Gy. This is the range established to be effective for radioactivity. See specification at page 20, lines 3-11. The Examiner notes that this range of the therapeutic dose of radiation (70-100Gy.) has been identified to be suitable with respect to the filler “collagen”. It has been interpreted that this therapeutic dose range of 70-100Gy. would also be required and effective for fillers other than the exemplified “collagen” filler.

Response to Arguments

Applicant's arguments see response on pages 7-20 filed 08/18/08, with respect to the 35 U.S.C. §112, 1st paragraph rejections of claims 17, 19, 21-24 and 29-38 are acknowledged. The 35 U.S.C. 112, 1st paragraph rejection of claims 17, 19, 21-24 and 29-38 based on lack of enablement for the specific fillers (i.e., fillers of claim 21) has been maintained since the NPL Articles, Patents and Declaration of Dr. Sawhney with citation to published articles (*I.J. Radiation Oncology*) filed 8/18/08 has not been provided on an Information Disclosure Statement and thus has not been considered on the merits. The Examiner respectfully requests Applicant to provide this information in IDS format in order for the information to be considered.

Allowable Subject Matter

Claim 65 is allowed.

Note: Any claim dependent on independent claim 65 would also be allowable.

Conclusion

Claims 17, 19, 21-24, 33-38 and 71 are rejected.

Claims 29-32, 66-70, 72 and 73 have been withdrawn (non-elected subject matter).

Claims 1-16, 18, 20, 25-28 and 39-64 are cancelled.

Claim 65 is allowable.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday-Friday during regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Humera N. Sheikh/

Primary Examiner, Art Unit 1615

hns

July 20, 2009

